

This is an official

CDC Health Advisory

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Important Safety Information - Revised Directions for Using Rabies Immune Globulin (Human), HyperRAB™ S/D in Fixed Needle 2 mL Pre-filled Syringe

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have been notified by Talecris Biotherapeutics, Inc. that its Rabies Immune Globulin (Human), HyperRAB™ S/D in fixed needle 2 mL pre-filled syringe does not address all dosing situations. Specifically, the fixed needle (22 gauge, 1.25 inch) and the absence of graduations on the 2 mL pre-filled syringe do not permit administration of the recommended dose of Rabies Immune Globulin (Human), HyperRAB™ S/D in one or more of the following situations:

- A dose < 2 mL is required (e.g. for pediatric use);
- A dose < 2 mL must be injected over multiple sites; or
- An alternate needle (different length or gauge) is required based on the patient (adult or child), wound or site of injection.

Three lots of HyperRAB™ S/D have been manufactured with the 2 mL pre-filled syringe configuration (see Table below):

Lot Number	Expiration Date	Size/Container	NDC Number
26N87R1	26-2009	2 mL pre-filled syringe	13533-618-03
26N88K1	Jan-26-2009	2 mL pre-filled syringe	13533-618-03
26N9HP1	Feb-18-2010	2 mL pre-filled syringe	13533-618-03

Human rabies PEP (post-exposure prophylaxis) is recommended when potentially infectious material (e.g. saliva) from a rabid animal is introduced via a bite, or comes into direct contact with broken skin or mucous membranes.

Healthcare providers may continue to administer HyperRAB™ S/D supplied in the 2 mL pre-filled syringe in the situations listed above by following the "Revised Directions for Use" that are packaged with these lots.

The full "Revised Directions for Use" of these lots is available on-line:

http://www.talecris.com/us/documents/FINAL_FDA_Approved_Revised_Directions_for_Syringe_Use_21-FEB-08.pdf. Talecris has discontinued manufacturing the HyperRAB™ S/D fixed needle, 2 mL pre-filled syringe.

For additional information

- Contact Talecris on-line at www.talecris.com, or call 919-412-1030, or toll free at 1-800-520-2807 for more information regarding this product.
- More detailed information regarding evaluation for and administration of PEP is available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056176.htm>.
- For more information about rabies and its prevention, contact your state or local public health officials (see contact numbers below) or CDC at 1-800-CDC-INFO or visit www.cdc.gov/rabies.

DHEC Contact Information for Reportable Diseases and Reporting Requirements

Reporting of animal (mammal) bites is included in the current DHEC List of Reportable Conditions as an "Immediately Reportable Condition". Healthcare providers are required to report suspected or confirmed cases to their Regional Public Health Offices, at the contact numbers listed below.

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2008

Mail or call reports to the Epidemiology Office in each Public Health Region.

Region 1

Anderson, Oconee

220 McGee Road
Anderson, SC 29625
Phone: (864) 260-4358
Fax: (864) 260-5623
Nights / Weekends: 1-866-298-4442

Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda

1736 S. Main Street
Greenwood, SC 29646
Phone: 1-888-218-5475
Fax: (864) 942-3690
Nights / Weekends: 1-800-420-1915

Region 2

Greenville, Pickens

PO Box 2507
200 University Ridge
Greenville, SC 29602-2507
Phone: (864) 282-4139
Fax: (864) 282-4373
Nights / Weekends: 1-800-993-1186

Cherokee, Spartanburg, Union

PO Box 4217
151 E. Wood Street
Spartanburg, SC 29305-4217
Phone: (864) 596-2227, x- 210
Fax: (864) 596-3443
Nights / Weekends: 1-800-993-1186

Region 3

Chester, Lancaster, York

PO Box 817
1833 Pageland Highway
Lancaster, SC 29721
Phone: (803) 286-9948
Fax: (803) 286-5418
Nights / Weekends: 1-866-867-3886

Region 3 (continued)

Fairfield, Lexington, Newberry, Richland

2000 Hampton Street
Columbia, SC 29204
Phone: (803) 576-2749
Fax: (803) 576-2993
Nights / Weekends: 1-888-554-9915

Region 4

Clarendon, Kershaw, Lee, Sumter

PO Box 1628
105 North Magnolia Street
Sumter, SC 29150
Phone: (803) 773-5511
Fax: (803) 775-9941
Nights/Weekends: 1-877-831-4647

Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion

145 E. Cheves Street
Florence, SC 29506
Phone: (843) 661-4830
Fax: (843) 661-4859
Nights / Weekends: (843) 660-8145

Region 5

Bamberg, Calhoun, Orangeburg

PO Box 1126
1550 Carolina Avenue
Orangeburg, SC 29116
Phone: (803) 533-7199
Fax: (803) 533-7134
Nights / Weekends: (803) 954-8513

Aiken, Allendale, Barnwell

1680 Richland Avenue, W. Suite 40
Aiken, SC 29801
Phone: (803) 642-1618
Fax: (803) 643-8386
Nights / Weekends: (803) 827-8668 or
1-800-614-1519

Region 6

Georgetown, Horry, Williamsburg

1931 Industrial Park Road
Conway, SC 29526-5482
Phone: (843) 915-8804
Fax: (843) 365-0085
Nights / Weekends: (843) 381-6710

Region 7

Berkeley, Charleston, Dorchester

4050 Bridge View Drive, Suite 600
N. Charleston, SC 29405
Phone: (843) 746-3860
Fax: (843) 746-3851
Nights / Weekends: (843) 219-8470

Region 8

Beaufort, Colleton, Hampton, Jasper

219 S. Lemacks Street
Walterboro, SC 29488
Phone: (843) 549-1516, x-214
Fax: (843) 549-6845
Nights / Weekends: 1-800-614-4698

DHEC Bureau of Disease Control

Division of Acute Disease Epidemiology

1751 Calhoun Street
Box 101106
Columbia, SC 29211
Phone: (803) 898-0861
Fax: (803) 898-0897
Nights / Weekends: 1-888-847-0902



www.scdhec.gov

Categories of Health Alert messages:

Health Alert conveys the highest level of importance; warrants immediate action or attention.

Health Advisory provides important information for a specific incident or situation; may not require immediate action.

Health Update provides updated information regarding an incident or situation; unlikely to require immediate action